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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/002,933	11/01/2001	Jeong S. Lee	ACSC 60355 (2750)	5440

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EXAMINER	
MCKANE, ELIZABETH L	
ART UNIT	**PAPER NUMBER**
1744	

DATE MAILED: 03/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/002,933	LEE ET AL.	
	Examiner	Art Unit	
	Leigh McKane	1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 February 2005* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5,7-12,14-23 and 27-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *27-32 and 35-37* is/are allowed.

6)☒ Claim(s) *1-3,5,7-12 and 14-21* is/are rejected.

7)☒ Claim(s) *22 and 23* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

1. Prosecution on the merits of this application is reopened on claims 1-3, 5, 7-12, 21-23, 33, and 34 considered unpatentable for the reasons indicated below.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-3 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Sun et al (U.S. Patent No. 5,728,748).

Sun et al teaches a method of sterilizing a medical device component (polymeric medical Implant material) wherein the sterilization process includes the steps of purging the polymeric material and irradiating the device with e-beam radiation in an inert gas filled container. The purging step occurs prior to forming the device wherein a container holding the polymer resin powder may be evacuated and an inert gas is used to then flush the container (col.4, line 66 to col.5, line 19). Afterwards the resin is formed into an implant in an inert atmosphere (col.5, lines 20-33). After forming the implant, it is placed into an airtight container in an oxidant-free atmosphere, accomplished by flushing the package with an inert gas and sealing the container. Subsequently, the implant within the sealed container is sterilized with e-beam radiation at a dose of 2.5 Mrad ("about 3 Mrad").

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sun et al.

Sun et al is silent with respect to a treatment time or to using multiple does. However, it would have been obvious to apply the e-beam radiation a for a length of time and for a sufficient number of times in order to achieve sterilization based upon the expected level of contamination and the particular polymeric material being treated. This is readily determinable by routine experimentation.

Moreover, although Sun et al does not expressly disclose sterilization of the claimed polymers in claim 12, it is taught by Sun et al that "all the theories and processes described hereafter should also apply to other polymer materials..." (see col.3, lines 44-46). Thus, it is deemed obvious to apply the method of Sun et al to the sterilization of other polymeric materials.

6. Claims 5, 7, 8, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sun et al in view of Chen et al (U.S. Patent No. 5,849,846).

Sun et al teaches a method of sterilizing a medical device component (polymeric medical implant material) wherein the sterilization process includes the steps of purging the polymeric material and irradiating the device with e-beam radiation in an inert gas filled container. The purging step occurs prior to forming the device wherein a container holding the polymer resin powder may be evacuated and an inert gas is used to then flush the container (col.4, line 66 to

col.5, line 19). Afterwards the resin is formed into an implant in an inert atmosphere (col.5, lines 20-33). After forming the implant, it is placed into an airtight container in an oxidant-free atmosphere, accomplished by flushing the package with an inert gas and sealing the container. Subsequently, the implant within the sealed container is sterilized with e-beam radiation. The medical device sterilized by the method of Sun et al is not a catheter shaft or catheter balloon. Chen et al teaches a method of strengthening a medical device component wherein the component (e.g. dilation catheter tubing material for balloons and catheters) is irradiated with an electron beam (col.9, lines 21-45) to improve the performance characteristics of the component. As the medical device of Chen et al will have to eventually undergo sterilization and as it is clearly capable of absorbing large doses of e-beam radiation without damage, it would have been obvious to use the method of Sun et al to sterilize the catheter of Chen et al.

Moreover, since Sun et al. discloses that it is imperative to remove all oxygen from the medical device before irradiation in order to prevent free radical oxidation of the polymeric material (col.2, lines 56-67; col.4, lines 4-6 and 54-65) it would have been obvious to one of ordinary skill in the art to purge the catheter of Chen et al in the manner disclosed by Sun et al wherein the medical device is filled with an inert gas. In addition, as Sun et al teaches performing all operations (purging, device forming, machining, sterilization) within an inert atmosphere, one would have found it obvious to accomplish the method of Sun et al with Chen et al within an inert atmosphere, such as within an inert gas filled chamber.

7. Claims 33 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sun et al in view of Chen et al and Lee et al.

Sun et al teaches a method of sterilizing a medical device component (polymeric medical

implant material) wherein the sterilization process includes the steps of purging the polymeric material and irradiating the device with e-beam radiation in an inert gas filled container. The purging step occurs prior to forming the device wherein a container holding the polymer resin powder may be evacuated and an inert gas is used to then flush the container (col.4, line 66 to col.5, line 19). Afterwards the resin is formed into an implant in an inert atmosphere (col.5, lines 20-33). After forming the implant, it is placed into an airtight container in an oxidant-free atmosphere, accomplished by flushing the package with an inert gas and sealing the container. Subsequently, the implant within the sealed container is sterilized with e-beam radiation. The medical device sterilized by the method of Sun et al is not a catheter shaft or catheter balloon.

Chen et al teaches a method of strengthening a medical device component wherein the component (e.g. dilation catheter tubing material for balloons and catheters) is irradiated with an electron beam (col.9, lines 21-45) to improve the performance characteristics of the component. As the medical device of Chen et al will have to eventually undergo sterilization and as it is clearly capable of absorbing large doses of e-beam radiation without damage, it would have been obvious to use the method of Sun et al to sterilize the catheter of Chen et al.

Sun et al and Chen et al together fail to disclose that the balloon catheter is a stent delivery balloon catheter. However, Lee et al teaches a stent delivery balloon catheter comprising a stent which may be metallic. See page 10, lines l 1-18. lt would have been obvious to employ the method of the combination to sterilize assembled stent delivery systems as they must be in a sterile state before use. As to the limitation requiring that "electron beam penetration into sections of the balloon located directly underneath the stent is reduced by the

metal of the metallic stent," this is a natural occurrence of radiation sterilization, as the balloon will be shadowed by the stent, regardless of whether the stent is metal or a non-mètal.

Allowable Subject Matter

8. Claims 22 and 23 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

9. Claims 27-31, 32, and 35-37 are allowed.

10. The following is a statement of reasons for the indication of allowable subject matter and allowance: With respect to dependent claims 22 and 23 and independent claims 27 and 32, Sun et al does not address the issue of rupture pressure or fatigue resistance as the implant being sterilized by Sun et al is not a catheter. While Chen et al does address rupture pressure and fatigue resistance, it is clearly taught by Chen et al that the purpose of the irradiation is to *increase* the rupture pressure and fatigue resistance of the catheter balloon. Therefore, the prior art of record fails to teach or suggest a method of sterilization wherein the rupture pressure or fatigue resistance after sterilization is less than or equal to the rupture pressure before sterilization.

Conclusion

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh McKane whose telephone number is 571-272-1275. The examiner can normally be reached on Monday-Wednesday (6:30 am-4:00 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Kim can be reached on 571-272-1142. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Leigh McKane

Leigh McKane
Primary Examiner
Art Unit 1744

elm
6 March 2005